

Office Action Summary	Application No. 10/506,315	Applicant(s) PAULY ET AL.	
	Examiner RACHAEL E. WELTER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>4/15/09</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/05</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of fructose as sugar, fructose caprate as a specific species of sugar fatty acid ester (monoesters and diesters), and an average degree of esterification of 2 in the reply filed on 4/30/2009 is acknowledged. Therefore, the election of species is deemed proper and is made FINAL. Applicant indicated in the reply that claims 17-22 and 25-30 read on the elected species. As such, claims 17-22 and 25-30 will be under consideration in the instant office action.

In searching for art on the elected invention, the examiner found and applied art (see below), which reads on the broader scope of the elected claims. This application of art should not be construed as a withdrawal of the species election.

Claim Status

Claims 17-30 are pending. Claims 1-16 are cancelled. Claims 17-22 and 25-30 are drawn to the elected species. Claims 23-24 are withdrawn.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 21, 2005 was in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statement was considered by the examiner. A signed copy of form 1449 is enclosed herewith. The examiner notes that reference, FR 2696467 was listed twice on form 1449. Therefore, the examiner did not consider the reference twice.

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Furthermore, the Falbe (Catalysts, Surfactants and Mineral Oil Additives) reference and the "Kosmetische Farbemittel" reference were not considered because they were not accompanied with an English translation.

Foreign Priority

Acknowledgement is made of applicant's foreign priority claim to EP 02290508.7 filed 3/1/2002. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –294403

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19, 21, and 25-26 rejected under 35 U.S.C. 102(b) as being anticipated by Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025).

Handa et al teach a pharmaceutical composition for the external treatment of skin wounds comprising 2-40 wt.% of the total weight of the composition of a mono- or dissacharide fatty acid ester and a prophylactically effective amount of an antiinfective agent (column 2, lines 31-43). According to Handa et al, the sugar moiety of said sugar fatty acid ester can be fructose, sucrose, lactose, and sugar alcohols (column 2, lines 44-47) and the fatty acid moiety is a fatty acid saturated or unsaturated fatty acid containing 6-22 carbon atoms (claim 3), such as palmitic acid, lauric acid, oleic acid, etc (column 2, lines 47-52). In example 5, Handa et al teach an ointment comprising sucrose fatty acid ester (DK Ester F-160) (column 6, lines 21-22). As evidenced by Jaspers et al, according to Table 2 (corrected percentage), DK F-160 has an average degree of esterification from approximately 1.23-1.46 (pg. 1022).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 20, 22, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025).

The disclosure of Handa et al is discussed above. The examiner notes that Handa et al suggest sugar moieties such as fructose and fatty acid moieties having from 8-16 carbon atoms, which include caprylic acid, lauric acid, myristic acid, and palmitic acid.

Although Handa et al suggest the use of both fructose as a sugar moiety and fatty acid moieties with 8-16 carbon atoms, it is not immediately envisaged and therefore the instant rejection is made under obviousness.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Handa et al and incorporate such moieties in the pharmaceutical composition. One would have been motivated to do so since Handa et al suggest the use of fructose palmitate, fructose myristate, etc as suitable alternatives among sugar fatty acid esters. Furthermore, it is within the skill of

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an artisan to select a given sugar fatty acid ester depending on costs, availability, and its degree in treating skin wounds such as a pressure sore.

Regarding claims 27-29, wherein the amount of sugar ester is present from 0.0001-10 wt.% and more specifically 0.01-1 wt.% based on the composition, the examiner notes that Handa et al teach an amount from 2-40 wt.%. Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the sugar fatty acid ester taught in the pharmaceutical composition of Handa et al. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results of effectively treating skin wounds. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05. The examiner notes that applicant can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range.

Regarding claim 30, wherein the composition comprises a plurality of sugar esters, the examiner notes that Handa et al do not explicitly teach a composition comprising more than one sugar ester. However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add more than one sugar ester to the composition of Handa et al. One would have been motivated to do so in order to possibly enhance the effect of treating skin tissue surrounding a pressure sore. Furthermore, the examiner notes that one would expect that a composition comprising

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two or more sugar esters would result in a complementary or possibly synergistic effect.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-18 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending

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Application No. 12/294,203. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending claims are drawn to a skin whitening composition comprising a sugar fatty acid ester, wherein the fatty acid moiety RCO is a linear or branched, saturated or unsaturated acyl or hydroxyacyl group having from 6-22 carbon atoms. The sugar is selected from the group consisting of monosaccharides, disaccharides, and mixtures thereof. The sugar ester along with a plant extract can be present in a concentration from 0.1-10 wt.% of the composition. The copending claims further claim a method of applying the composition to the skin.

Thus, the copending claims anticipate the method of instant claims 17-18 and 21.

Furthermore, because the instant claims recite “a composition comprising...”, the claims are inclusive or open-ended and do not exclude additional, unrecited elements or method steps, such as a plant extract and an additional skin whitening agent. See MPEP 2111.03.

Claims 19-20, 22, and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 12/294,203 in view of Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Although the copending claims are drawn to a sugar fatty acid ester, the copending claims are not explicitly drawn to a sugar selected from fructose, glucose, trehalose, sucrose, and mixtures thereof.

Handa et al teach a pharmaceutical composition for the external treatment of skin comprising 2-40 wt.% of the total weight of the composition of a mono- or dissacharide fatty acid ester and a prophylactically effective amount of an antiinfective agent (column 2, lines 31-43). According to Handa et al, the sugar moiety of said sugar fatty acid ester can be fructose, sucrose, lactose, and sugar alcohols (column 2, lines 44-47) and the fatty acid moiety is a fatty acid saturated or unsaturated fatty acid containing 6-22 carbon atoms (claim 3), such as palmitic acid, lauric acid, oleic acid, etc (column 2, lines 47-52). In example 5, Handa et al teach an ointment comprising sucrose fatty acid ester (DK Ester F-160) (column 6, lines 21-22). As evidenced by Jaspers et al, according to Table 2 (corrected percentage), DK F-160 has an average degree of esterification from approximately 1.23-1.46 (pg. 1022). Handa et al further suggest sugar moieties such as fructose and fatty acid moieties having from 8-16 carbon atoms, which include caprylic acid, lauric acid, myristic acid, and palmitic acid.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use sugars, such as fructose, sucrose, and lactose as taught in Handa et al. One would have been motivated to do so since Handa et al teach that such sugar fatty acid esters are safe and can be used to treat the skin. Furthermore, Handa et al teach that sucrose fatty acid ester is preferred, more specifically DK F-160 with an average esterification degree of approximately 1.23-1.46, because it is

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commonly used in food and drug products available from commercial sources (column 2, lines 52-55--column 3, lines 1-2; example 5).

Regarding instant claims 27-29, wherein the amount of sugar ester is present from 0.0001-10 wt.% and more specifically 0.01-1 wt.% based on the composition, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the sugar fatty acid ester in the copending claims. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05.

Regarding instant claim 30, wherein the composition comprises a plurality of sugar esters, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add more than one sugar ester to the composition of the copending claims. One would have been motivated to do so in order to possibly enhance the skin whitening effect of the composition in the copending claims. The examiner notes that one would expect that a composition comprising two or more sugar esters would result in a complementary or possibly synergistic effect. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

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individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claims 17-22 and 25-30 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
July 5, 2009